Newborn Screening Quality Assurance Program

QUALITY CONTROL

Midyear Report
Inborn Errors of Metabolism

Volume 14, No. 1 June 2003

INTRODUCTION

The Newborn Screening Quality Assurance Program (NSQAP), Centers for Disease Control and Prevention (CDC), distributed dried-blood-spot (DBS) quality control (QC) materials for thyroxine (T_4), thyroid-stimulating hormone (TSH), 17 α-hydroxyprogesterone (17-OHP), total galactose (Gal), phenylalanine (Phe), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), and citrulline (Cit) to laboratories operating newborn screening programs and to manufacturers of screening test products. Included with each semiannual shipment of QC specimens was a data-report form to be completed and returned to CDC.

This midyear report contains a summary of the QC data submitted during the first half of 2003 by state, contract, and private laboratories in the United States; international participants; and manufacturers of screening test products.

---- QC DATA ----
see pages 3-13

QUALITY CONTROL MATERIALS

The QC specimen lots were provided as 6-month supplies of DBSs on filter paper. All DBS QC lots were prepared from whole blood of 55% hematocrit with lysed red blood cells. The QC materials were enriched with predetermined quantities of the selected analytes and dispensed in 100 µL aliquots on Schleicher & Schuell (Keene, NH) Grade 903 filter paper.

A QC shipment for T_4, TSH, or 17-OHP consisted of blood-spot materials from three lots per analyte, with each lot containing a different concentration of analyte. A QC shipment for Gal, Phe, Leu, Met, Tyr, Val, and Cit consisted of blood-spot cards from four different lots.

The QC materials were supplied for use as external controls in quantities sufficient to maintain continuity and transcend changes in production lots of routinely used method- or kit-control materials. The external QC materials were intended to supplement the participants' method- or kit-control materials at periodic intervals and to allow participants to monitor the long-term stability of their assays. The QC materials should not be used as routine daily QCs.

PARTICIPANTS' RESULTS

For this midyear report, we compiled the data that each participant reported from five analytic runs of specimens from each QC lot and calculated mean values and standard deviations from these data. Data values outside the 99% confidence interval for each QC lot were not included in the computations. We could not include qualitative data, data submitted as inequalities or ranges, data submitted in unidentified units, or data from more than five analytic runs per specimen lot per participant. Some participants submitted results in units other than those requested on the data-report forms. To ensure that all results are appropriately entered in the CDC database, participants should convert their results to the requested units before entering them on the data-report forms.

The reported QC data are summarized in tables on pages 3-13, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the standard deviations (SD) by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Results of the linear

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regression analyses are summarized in the tables on pages 3-13.

DISCUSSION

The enriched values of the QC specimen lots, shown in the tables for each lot, do not take into account the endogenous levels of the analytes; however, analytic results indicate that endogenous concentrations are negligible for all analytes except Phe, Leu, Met, Tyr, Val, and Cit. For Phe, Leu, Met, Tyr, Val, and Cit, the nonenriched base pools were distributed as the first QC specimen lot in each series so that participants could measure the endogenous Phe, Leu, Met, Tyr, Val, and Cit concentration of the series. QC lots 245-248 were enriched with Gal, Phe, Leu, Met, Tyr, Val, and Cit; all other QC lots were enriched with one analyte per lot. Gal lots 245-248 were enriched with equimolar quantities of simple galactose and galactose-1-phosphate.

The tables, which summarize reported QC results (pages 3-13), provide data for method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from a single batch of hematocrit-adjusted, nonenriched blood, the endogenous concentration was the same for all specimens in a lot series. For the first half of 2003, we calculated the within-laboratory SD component of the total SD. The reported QC data from multiple analytic runs were used for regression analyses. We calculated the Y-intercept and slope listed in each table using all analyte concentrations within a lot series (e.g., lots 101, 102, and 103). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. When mean values for QC lots for four of the T_4 methods were compared with mean values for the other T_4 methods, a low bias was observed for these four methods even though the Y-intercepts and slopes were reasonable. For Phe, Leu, Met, Tyr, Val, and Cit, participants measured the endogenous concentration levels by analyzing the nonenriched QC lots. When endogenous levels were compared for these amino acids, we found them to be similar for all Phe methods; but the range of values for the other amino acids was greater among methods than expected for the nonenriched QC lots. Ideally, the slope should be 1.0 for each method. The slopes for most methods were close to this value, but some were a bit further away. For example, for one Gal method, the slope was 0.6; for another Gal method, the slope was 1.4; and for one Cit method, the slope was 0.7. Unlike the data reported during the last two years, the slopes for all 17-OHP methods were reasonable. These slope deviations may be related to analytic ranges for calibration curves. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate that a method has an analytic bias.

Each year, with the extensive cooperation of Schleicher & Schuell, Inc. (S&S) and Whatman Inc., we routinely monitor the absorption characteristics of approved filter papers. (Participants may refer to page 6 of the 2003 NSQAP Summary Report[1] for charts of the serum absorbancies of 19 Grade 903 filter paper lots and to page 7 for charts of the serum absorbancies of eight BFC 180 filter paper lots that CDC monitored.) The following S&S filter paper lots were used in the production of QC specimen lots distributed during the first 6 months of 2003: W981 (Lots 101-103, 211-213, 151-153) and W001 (Lots 245-248).

1. Bell CJ, editor. Newborn Screening Quality Assurance Program: 2002 Annual Summary Report. Atlanta: Centers for Disease Control and Prevention, 2003;20:1-49.

2003 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (µg T_4/dL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 101 - Enriched 2 µg/dL serum						
Diagnostic Products	10	2.4	0.3	0.3	0.7	0.8
ICN Biomedicals RIA	29	2.7	0.3	0.5	1.1	0.8
Neometrics Accuscreen	10	3.2	0.2	0.2	0.8	1.1
Neometrics Neocoat	39	2.4	0.4	0.4	0.5	1.0
Neometrics Accuwell	49	2.5	0.6	0.8	0.5	1.0
Delfia	86	2.1	0.5	0.9	0.6	0.8
AutoDelfia	215	2.1	0.4	0.6	0.3	0.9
Other	20	2.5	0.4	0.5	0.5	1.0
Lot 102 - Enriched 5.5 µg/dL serum						
Diagnostic Products	10	5.0	0.7	0.7	0.7	0.8
ICN Biomedicals RIA	30	5.6	0.7	0.8	1.1	0.8
Neometrics Accuscreen	10	6.4	0.9	0.9	0.8	1.1
Neometrics Neocoat	39	5.8	0.7	0.7	0.5	1.0
Neometrics Accuwell	49	5.8	0.9	0.9	0.5	1.0
Delfia	80	5.3	0.8	0.9	0.6	0.8
AutoDelfia	213	5.2	0.8	1.6	0.3	0.9
Other	20	5.9	0.7	0.7	0.5	1.0
Lot 103 - Enriched 8 µg/dL serum						
Diagnostic Products	10	7.3	0.9	0.9	0.7	0.8
ICN Biomedicals RIA	30	7.4	0.5	0.7	1.1	0.8
Neometrics Accuscreen	10	10.0	0.9	0.9	0.8	1.1
Neometrics Neocoat	40	8.1	1.0	1.0	0.5	1.0
Neometrics Accuwell	49	8.4	1.1	1.1	0.5	1.0
Delfia	89	7.0	1.1	1.2	0.6	0.8
AutoDelfia	212	7.4	1.1	2.2	0.3	0.9
Other	20	8.4	1.1	1.1	0.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μIU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 211 - Enriched 25 μIU/mL serum						
Diagnostic Products	30	28.2	2.4	4.6	2.2	1.0
Neometrics Accuscreen	20	23.5	5.3	5.9	-0.7	1.0
Neometrics Accuwell	50	23.3	3.4	6.7	2.8	0.8
ICN Biomedicals IRMA	60	30.9	3.1	5.0	4.8	1.0
ICN Biomedicals ELISA	49	26.7	1.9	2.4	6.0	0.8
Delfia	428	24.5	4.5	5.8	0.4	1.0
AutoDelfia	449	25.1	2.4	3.5	0.5	1.0
Thermo Labsystems	29	27.3	3.2	3.4	2.0	1.1
In House	96	24.7	3.0	7.0	0.2	1.0
Other	403	28.8	3.6	9.6	1.8	1.1
Lot 212 - Enriched 40 μIU/mL serum						
Diagnostic Products	30	43.9	3.4	7.4	2.2	1.0
Neometrics Accuscreen	20	39.6	4.7	6.9	-0.7	1.0
Neometrics Accuwell	49	34.3	5.9	8.9	2.8	0.8
ICN Biomedicals IRMA	60	45.6	3.4	6.6	4.8	1.0
ICN Biomedicals ELISA	49	39.3	2.6	2.6	6.0	0.8
Delfia	403	40.7	5.3	8.0	0.4	1.0
AutoDelfia	449	40.2	4.1	5.5	0.5	1.0
Thermo Labsystems	30	46.1	5.4	8.5	2.0	1.1
In House	98	41.4	4.7	10.2	0.2	1.0
Other	401	45.7	5.5	14.7	1.8	1.1
Lot 213 - Enriched 80 μIU/mL serum						
Diagnostic Products	29	85.5	7.3	9.4	2.2	1.0
Neometrics Accuscreen	20	78.3	8.2	10.0	-0.7	1.0
Neometrics Accuwell	50	67.1	7.2	19.0	2.8	0.8
ICN Biomedicals IRMA	60	87.5	6.3	8.2	4.8	1.0
ICN Biomedicals ELISA	50	72.5	3.7	7.7	6.0	0.8
Delfia	406	79.1	9.3	15.0	0.4	1.0
AutoDelfia	449	79.6	7.1	9.7	0.5	1.0
Thermo Labsystems	30	86.4	6.1	15.8	2.0	1.1
In House	98	80.4	10.3	19.3	0.2	1.0
Other	403	88.9	9.1	24.5	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

17 α-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 151 - Enriched 25 ng/mL serum						
ICN Biomedicals RIA	19	26.4	2.7	2.8	6.4	0.9
Neometrics Accuscreen	20	27.9	3.6	3.6	5.9	0.9
Neometrics Accuwell	29	25.8	3.7	3.9	3.0	0.9
Delfia	117	26.3	3.2	6.4	2.0	1.0
AutoDelfia	246	28.6	3.0	4.5	2.5	1.0
Bayer Medical EIA	10	29.7	3.7	3.7	9.6	0.8
In House	10	24.9	2.8	2.8	2.2	0.9
Other	30	27.6	2.3	4.6	7.9	0.9
Lot 152 - Enriched 50 ng/mL serum						
ICN Biomedicals RIA	20	53.8	3.5	7.2	6.4	0.9
Neometrics Accuscreen	20	54.2	3.9	8.5	5.9	0.9
Neometrics Accuwell	29	50.4	7.3	8.6	3.0	0.9
Delfia	116	49.8	7.1	13.9	2.0	1.0
AutoDelfia	243	53.5	5.3	7.2	2.5	1.0
Bayer Medical EIA	10	52.0	6.0	6.0	9.6	0.8
In House	10	47.2	3.6	3.6	2.2	0.9
Other	30	53.8	4.4	7.6	7.9	0.9
Lot 153 - Enriched 100 ng/mL serum						
ICN Biomedicals RIA	20	94.0	8.0	8.0	6.4	0.9
Neometrics Accuscreen	20	98.3	6.3	6.9	5.9	0.9
Neometrics Accuwell	29	95.9	10.4	13.1	3.0	0.9
Delfia	118	98.3	13.7	27.3	2.0	1.0
AutoDelfia	245	105.5	11.7	16.8	2.5	1.0
Bayer Medical EIA	9	92.1	14.9	14.9	9.6	0.8
In House	10	92.6	6.5	6.5	2.2	0.9
Other	30	93.3	8.2	8.2	7.9	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
Fluorometric Manual	70	1.6	0.3	0.5	1.6	1.0
Bacterial Inhibition	150	1.6	0.2	0.7	1.7	0.9
Fluor Cont Flo, In-house	40	1.9	0.1	0.2	1.8	1.2
Fluor Cont Flo, Kit	110	1.9	0.2	0.6	1.8	1.1
Colorimetric	116	1.5	0.3	0.5	1.1	1.1
PerkinElmer Life Sciences	277	1.3	0.2	0.3	1.2	0.9
HPLC	78	1.4	0.2	0.2	1.4	1.0
Tandem Mass Spec	265	1.5	0.2	0.3	1.4	1.0
Neometrics Accuwell	70	1.4	0.3	0.4	1.1	1.1
Quantase (Bio-Rad)	108	1.5	0.4	0.7	1.0	1.0
ICN Biomed Enzyme Assay	10	1.5	0.4	0.4	1.6	0.9
Other	89	1.8	0.3	0.7	1.5	0.9
Lot 246 - Enriched 3 mg/dL whole blood						
Fluorometric Manual	69	4.8	0.8	0.9	1.6	1.0
Bacterial Inhibition	167	4.4	0.6	0.9	1.7	0.9
Fluor Cont Flo, In-house	40	5.3	0.4	0.9	1.8	1.2
Fluor Cont Flo, Kit	110	5.0	0.4	1.0	1.8	1.1
Colorimetric	120	4.2	0.6	0.9	1.1	1.1
PerkinElmer Life Sciences	273	3.8	0.5	0.5	1.2	0.9
HPLC	88	4.3	0.4	0.6	1.4	1.0
Tandem Mass Spec	264	4.3	0.4	0.7	1.4	1.0
Neometrics Accuwell	69	4.3	0.5	0.7	1.1	1.1
Quantase (Bio-Rad)	120	3.9	0.5	1.0	1.0	1.0
ICN Biomed Enzyme Assay	10	4.1	0.5	0.5	1.6	0.9
Other	97	4.2	0.5	0.8	1.5	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 247 - Enriched 7 mg/dL whole blood						
Fluorometric Manual	69	8.9	0.9	1.4	1.6	1.0
Bacterial Inhibition	170	8.0	0.9	1.4	1.7	0.9
Fluor Cont Flo, In-house	40	10.0	0.7	1.9	1.8	1.2
Fluor Cont Flo, Kit	108	9.4	1.0	1.8	1.8	1.1
Colorimetric	120	8.2	0.9	2.0	1.1	1.1
PerkinElmer Life Sciences	274	7.3	0.8	0.9	1.2	0.9
HPLC	79	8.6	0.6	1.0	1.4	1.0
Tandem Mass Spec	262	8.2	0.8	1.5	1.4	1.0
Neometrics Accuwell	70	7.9	1.0	1.4	1.1	1.1
Quantase (Bio-Rad)	120	7.2	0.8	2.1	1.0	1.0
ICN Biomed Enzyme Assay	10	7.7	0.4	0.4	1.6	0.9
Other	96	7.9	0.6	1.3	1.5	0.9
Lot 248 - Nonenriched 11 mg/dL whole blood						
Fluorometric Manual	69	13.1	1.7	2.0	1.6	1.0
Bacterial Inhibition	166	11.2	1.2	2.0	1.7	0.9
Fluor Cont Flo, In-house	40	15.3	0.9	2.7	1.8	1.2
Fluor Cont Flo, Kit	107	13.9	1.2	2.8	1.8	1.1
Colorimetric	120	13.8	1.1	2.2	1.1	1.1
PerkinElmer Life Sciences	273	11.0	1.1	1.2	1.2	0.9
HPLC	88	12.4	1.1	2.2	1.4	1.0
Tandem Mass Spec	261	12.1	1.1	2.3	1.4	1.0
Neometrics Accuwell	69	13.6	1.4	2.4	1.1	1.1
Quantase (Bio-Rad)	120	12.9	1.3	2.9	1.0	1.0
ICN Biomed Enzyme Assay	10	11.0	1.4	1.4	1.6	0.9
Other	97	12.0	0.9	2.0	1.5	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	60	1.8	0.5	1.0	2.0	0.8
PerkinElmer Life Sciences	30	2.2	0.4	0.7	1.7	1.0
HPLC	59	2.0	0.8	0.8	2.0	1.0
Tandem Mass Spec	241	2.2	0.3	0.6	2.1	0.9
Thin-Layer Chromatography	10	1.4	0.5	0.5	1.6	0.8
Other	19	1.1	0.3	1.7	0.2	1.0
Lot 246 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	60	4.5	0.7	1.5	2.0	0.8
PerkinElmer Life Sciences	29	4.4	0.7	0.9	1.7	1.0
HPLC	59	5.0	0.4	0.6	2.0	1.0
Tandem Mass Spec	239	4.6	0.6	1.2	2.1	0.9
Thin-Layer Chromatography	10	4.4	0.5	0.5	1.6	0.8
Other	20	2.6	1.0	2.0	0.2	1.0
Lot 247 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	59	7.8	0.9	2.1	2.0	0.8
PerkinElmer Life Sciences	30	8.3	0.9	1.5	1.7	1.0
HPLC	60	9.1	0.7	1.2	2.0	1.0
Tandem Mass Spec	240	8.2	1.1	2.1	2.1	0.9
Thin-Layer Chromatography	10	7.2	0.8	0.8	1.6	0.8
Other	20	5.6	1.1	1.3	0.2	1.0
Lot 248 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	50	10.4	0.9	2.1	2.0	0.8
PerkinElmer Life Sciences	30	13.5	1.8	1.9	1.7	1.0
HPLC	60	13.2	1.5	1.8	2.0	1.0
Tandem Mass Spec	239	11.7	1.4	3.0	2.1	0.9
Thin-Layer Chromatography	10	10.4	1.1	1.1	1.6	0.8
Other	20	11.7	1.5	3.2	0.2	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	60	0.5	0.3	0.4	0.6	1.2
HPLC	49	0.3	0.1	0.2	0.2	0.8
Tandem Mass Spec	239	0.4	0.1	0.1	0.3	0.8
Thin-Layer Chromatography	10	0.6	0.5	0.5	0.4	1.0
Lot 246 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	60	1.7	0.4	0.6	0.6	1.2
HPLC	48	1.0	0.2	0.3	0.2	0.8
Tandem Mass Spec	230	1.2	0.2	0.3	0.3	0.8
Thin-Layer Chromatography	10	1.6	0.5	0.5	0.4	1.0
Lot 247 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	59	4.7	0.9	2.1	0.6	1.2
HPLC	50	2.5	0.2	0.4	0.2	0.8
Tandem Mass Spec	236	2.8	0.5	0.9	0.3	0.8
Thin-Layer Chromatography	10	2.8	0.8	0.8	0.4	1.0
Lot 248 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	50	7.4	0.9	1.9	0.6	1.2
HPLC	50	5.1	0.5	0.6	0.2	0.8
Tandem Mass Spec	236	5.4	1.0	1.8	0.3	0.8
Thin-Layer Chromatography	10	6.8	1.2	1.2	0.4	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
HPLC	59	1.3	0.2	0.2	1.4	0.9
Tandem Mass Spec	245	1.2	0.1	0.2	1.2	0.9
Thin-Layer Chromatography	10	0.6	0.5	0.5	0.4	0.9
Other	49	1.5	0.2	0.5	1.5	1.0
Lot 246 - Enriched 2 mg/dL whole blood						
HPLC	68	3.3	0.3	0.4	1.4	0.9
Tandem Mass Spec	246	3.0	0.4	0.7	1.2	0.9
Thin-Layer Chromatography	10	2.4	0.5	0.5	0.4	0.9
Other	48	3.6	0.7	1.1	1.5	1.0
Lot 247 - Enriched 4 mg/dL whole blood						
HPLC	59	5.1	0.5	0.6	1.4	0.9
Tandem Mass Spec	240	4.6	0.5	1.3	1.2	0.9
Thin-Layer Chromatography	10	3.4	0.5	0.5	0.4	0.9
Other	50	5.4	0.6	1.1	1.5	1.0
Lot 248 - Enriched 8 mg/dL whole blood						
HPLC	70	8.6	0.7	1.1	1.4	0.9
Tandem Mass Spec	246	8.2	0.9	1.7	1.2	0.9
Thin-Layer Chromatography	10	7.8	0.8	0.8	0.4	0.9
Other	49	9.6	1.1	2.0	1.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

VALINE (mg Val/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
HPLC	39	2.1	0.2	0.4	2.2	0.8
Tandem Mass Spec	191	1.8	0.2	0.6	1.8	0.8
Thin-Layer Chromatography	10	0.8	0.4	0.4	1.3	0.8
Lot 246 - Enriched 1 mg/dL whole blood						
HPLC	40	3.1	0.3	0.4	2.2	0.8
Tandem Mass Spec	203	2.5	0.4	0.8	1.8	0.8
Thin-Layer Chromatography	10	2.2	0.4	0.4	1.3	0.8
Lot 247 - Enriched 3 mg/dL whole blood						
HPLC	40	4.8	0.4	0.7	2.2	0.8
Tandem Mass Spec	204	4.0	0.5	1.3	1.8	0.8
Thin-Layer Chromatography	10	4.4	0.5	0.5	1.3	0.8
Lot 248 - Enriched 6 mg/dL whole blood						
HPLC	40	7.2	0.6	1.3	2.2	0.8
Tandem Mass Spec	200	6.3	0.8	2.0	1.8	0.8
Thin-Layer Chromatography	10	5.8	0.8	0.8	1.3	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (mg Cit/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Nonenriched 0 mg/dL whole blood						
Tandem Mass Spec	194	0.5	0.1	0.2	0.5	0.8
Thin-Layer Chromatography	10	0.0	0.0	0.0	0.1	0.7
Lot 246 - Enriched 0.5 mg/dL whole blood						
Tandem Mass Spec	195	0.9	0.1	0.4	0.5	0.8
Thin-Layer Chromatography	10	0.6	0.5	0.5	0.1	0.7
Lot 247 - Enriched 1 mg/dL whole blood						
Tandem Mass Spec	193	1.3	0.2	0.6	0.5	0.8
Thin-Layer Chromatography	10	0.8	0.4	0.4	0.1	0.7
Lot 248 - Enriched 2.5 mg/dL whole blood						
Tandem Mass Spec	193	2.5	0.5	1.1	0.5	0.8
Thin-Layer Chromatography	10	1.8	0.4	0.4	0.1	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2003 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 245 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	120	4.9	1.1	1.9	-0.4	1.0
Bioassay	20	3.9	0.2	0.2	0.5	0.6
Fluor Cont Flo, Kit	70	7.0	0.7	1.1	1.1	1.1
Colorimetric	69	5.7	1.1	1.8	0.5	1.1
PerkinElmer Life Sciences	108	7.8	0.9	0.9	3.7	0.8
Neometrics Accuwell	29	6.5	1.1	1.7	-2.0	1.4
Quantase (Bio-Rad)	40	4.5	0.8	1.3	-2.5	1.0
Other	98	5.4	1.2	1.8	-1.2	1.2
Lot 246 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	117	9.6	1.2	2.2	-0.4	1.0
Bioassay	20	6.5	0.2	0.8	0.5	0.6
Fluor Cont Flo, Kit	69	12.0	1.1	1.5	1.1	1.1
Colorimetric	69	11.2	1.5	2.6	0.5	1.1
PerkinElmer Life Sciences	107	11.8	1.2	1.3	3.7	0.8
Neometrics Accuwell	30	12.4	1.4	2.5	-2.0	1.4
Quantase (Bio-Rad)	39	7.0	0.8	1.0	-2.5	1.0
Other	96	9.8	1.6	2.5	-1.2	1.2
Lot 247 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	116	15.3	1.3	2.3	-0.4	1.0
Bioassay	20	9.0	0.5	1.5	0.5	0.6
Fluor Cont Flo, Kit	67	17.6	1.5	2.4	1.1	1.1
Colorimetric	70	17.4	2.9	4.2	0.5	1.1
PerkinElmer Life Sciences	109	15.5	1.5	1.7	3.7	0.8
Neometrics Accuwell	30	17.0	1.8	2.0	-2.0	1.4
Quantase (Bio-Rad)	39	9.8	1.1	1.3	-2.5	1.0
Other	95	16.2	2.4	4.9	-1.2	1.2
Lot 248 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	115	30.5	2.3	4.1	-0.4	1.0
Bioassay	20	18.9	0.6	1.6	0.5	0.6
Fluor Cont Flo, Kit	70	34.7	2.8	4.6	1.1	1.1
Colorimetric	69	32.9	7.2	7.6	0.5	1.1
PerkinElmer Life Sciences	109	27.9	3.1	3.6	3.7	0.8
Neometrics Accuwell	30	41.7	4.7	10.8	-2.0	1.4
Quantase (Bio-Rad)	40	28.6	3.4	4.8	-2.5	1.0
Other	98	34.3	5.8	11.4	-1.2	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

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